510(k) Summary

APR 0 2 2014

Submitted on behalf of:
Company Name: BK Meditech Co, Ltd
Address: 215-5 Yodang-Li, Yanggam-Myun
Hwasung-Si, Kyunggi-Do
Republic of Korea 445-931
Telephone: 82-313529135
Fax: 82-313529134

by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **March 3, 2014**
TRADE NAME: **INNESIS PEEK CERVICAL CAGE**
COMMON NAME: **Intervertebral body fusion device**
DEVICE CLASSIFICATION **Class II**
CLASSIFICATION NAME: **Orthosis, Intervertebral body fusion device, cervical**
REDUALTION: **888.3080**
PRODUCT CODE: **ODP**

INDICATIONS FOR USE:
The INNESIS PEEK Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. INNESIS PEEK Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach and packed with autogenous bone. INNESIS PEEK Cervical Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

DESCRIPTION of the DEVICE:
The INNESIS PEEK Cervical Cage is an implant for the anterior stabilization of the cervical spinal column using an Anterior Cervical Desectomy and Fusion (ACDF) surgery. The INNESIS PEEK Cervical Cages are offered in a variety of heights, footprints and curved shapes. The INNESIS PEEK Cervical Cages have ridges or teeth that resist rotation and migration and have cavities to accept packing of bone graft. The INNESIS PEEK Cervical Cage includes spikes and marker (pin) for radiological evaluation of the position and orientation of the radiolucent PEEK Cage

SUBSTANTIALLY EQUIVALENCE DEMONSTRATED BY:
The subject and predicate devices are substantially equivalent in the areas of materials, design, indications for use and operational principles. Based on the comparison between the subject

510(k) Summary-Continued

and predicate devices, BK MEDITECH Co., Ltd. believes that the INNESIS PEEK Cervical Cages are substantially equivalent (as fully detailed in the submission) to predicate devices which include the following devices:

Company Name	Device Tradename	510(k) Number
BK MEDITECH Co., Ltd	INNESIS PEEK CAGE(lumbar)	K120464
Stryker Spine	Stryker Spine AVS® AS PEEK Spacer	K120486
Southern Spine, LLC	Southern Spine C-Fuse™ Cervical Intervertebral Body Fusion System	K130948
SpineCraft, LLC	ORIO Intervertebral Body Fusion Cage by	K090887
Medacta International, SA	Mecta-C	K112862
Custom Spine	PATHWAY ACIF	K092904
Biomet Spine	C-Thru™ Anterior Spinal System	K092336
BM Korea	SYNSTER® CERVICAL CAGE	K111820
Medicrea Technologies	IMPIX cervical interbody device	K072226

SUMMARY of TESTING:

Testing results are for the following:

- Static and dynamic axial compression test, conducted in accordance with ASTM F2077-03
- Static compression shear test, conducted in accordance with ASTM F2077-03
- Static and dynamic torsion test, conducted in accordance with ASTM F2077-03
- Static subsidence test, conducted in accordance with ASTM F2267-04
- Expulsion test, conducted in accordance with ASTM Draft Standard F04.25.02.02.

The material of the INNESIS PEEK Cervical Cage (permanent implant- long term) is PEEK (Polyetheretherketone, ASTM F2026) and Titanium Alloy (Ti6Al4V-ELI, ASTM F136). These materials are both recognized as suitable biomaterials for this intended use and predicate devices have previously been cleared by FDA for this same intended use. Endotoxin testing has demonstrated that the process does not introduce endotoxins as a bi-product of the manufacturing and cleaning process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2014

BK Meditech Co., Ltd.
% Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K132483
Trade/Device Name: INNESIS PEEK Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 3, 2014
Received: March 4, 2014

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132483

Device Name
INNESIS PEEK CERVICAL CAGE

Indications for Use *(Describe)*

The INNESIS PEEK Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. INNESIS PEEK Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach and packed with autogenous bone. INNESIS PEEK Cervical Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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